Attorney's Docker No.: 12071-003001 / SP-21 US Applicant: John R. Neefe et al.

Serial No.: 09/891,823 Filed

: June 26, 2001

Page

: 16

**Pending Claims** 

1. A method of treating a wart in a subject, the method comprising administering, to a subject who has been identified as having a wart, a composition comprising a fusion protein comprising (1) an Hsp60 protein or an immunostimulatory fragment thereof, and (2) a human papilloma virus (HPV) E7 protein or an antigenic fragment thereof, wherein the composition is administered in an amount sufficient to treat the wart, wherein the wart is caused by an infection with a first type of HPV, and wherein the HPV E7 protein or antigenic fragment thereof is of a second type of HPV that differs from the first type of HPV.

- 2. The method of claim 1, wherein the Hsp60 protein is a mycobacterial hsp.
- 3. The method of claim 2, wherein the mycobacterial hsp is a *Mycobacterium bovis* hsp.
- 4. The method of claim 3, wherein the Mycobacterium bovis hsp is Mycobacterium bovis BCG Hsp65.
  - 6. The method of claim 1, wherein the HPV is a type 16 HPV.
- 8. The method of claim 1, wherein the composition contains about 50 to 5000 µg of the fusion protein.
- 9. The method of claim 8, wherein the composition contains about 100 to 2000 µg of the fusion protein.
  - 10. The method of claim 1, wherein the composition is administered free of adjuvant.
  - 11. The method of claim 1, wherein the subject is a mammal.

Applicant: John R. Neefe et al. Attorney's Docker No.: 12071-003001 / SP-21 US

Serial No.: 09/891,823 Filed: June 26, 2001

Page : 17

12. The method of claim 11, wherein the mammal is a human.

13. The method of claim 1, wherein the fusion protein is administered in an amount sufficient to reduce the size of the wart.

- 36. The method of claim 1, wherein the wart is a genital wart.
- 37. The method of claim 1, wherein the wart is an anogenital wart.
- 38. The method of claim 1, wherein the composition comprises about 500  $\mu g$  of the fusion protein.
  - 39. The method of claim 1, wherein the fusion protein comprises the Hsp60 protein.
  - 40. The method of claim 39, wherein the Hsp60 protein is a mycobacterial hsp.
- 41. The method of claim 40, wherein the mycobacterial hsp is a *Mycobacterium bovis* hsp.
- 42. The method of claim 41, wherein the *Mycobacterium bovis* hsp is *Mycobacterium bovis* BCG Hsp65.
  - 43. The method of claim 39, wherein the HPV is a type 16 HPV.
- 44. The method of claim 39, wherein the composition contains about 50 to 5000  $\mu g$  of the fusion protein.
- 45. The method of claim 44, wherein the composition contains about 100 to 2000  $\mu g$  of the fusion protein.

Applicant: John R. Neefe et al. Attorney's Docket No.: 12071-003001 / SP-21 US

Serial No.: 09/891,823 Filed: June 26, 2001

Page : 18

46. The method of claim 39, wherein the composition comprises about 500  $\mu g$  of the fusion protein.

- 47. The method of claim 39, wherein the composition is administered free of adjuvant.
- 48. The method of claim 39, wherein the subject is a mammal.
- 49. The method of claim 48, wherein the mammal is a human.
- 50. The method of claim 39, wherein the fusion protein is administered in an amount sufficient to reduce the size of the wart.
  - 51. The method of claim 39, wherein the wart is a genital wart.
  - 52. The method of claim 39, wherein the wart is an anogenital wart.
  - 53. The method of claim 1, wherein the fusion protein comprises the HPV E7 protein.
  - 54. The method of claim 53, wherein the Hsp60 protein is a mycobacterial hsp.
- 55. The method of claim 54, wherein the mycobacterial hsp is a *Mycobacterium bovis* hsp.
- 56. The method of claim 55, wherein the *Mycobacterium bovis* hsp is *Mycobacterium bovis* BCG Hsp65.
  - 57. The method of claim 53, wherein the HPV is a type 16 HPV.

Applicant: John R. Neefe et al.

Serial No.: 09/891,823 Filed

: June 26, 2001

Page

: 19

58. The method of claim 53, wherein the composition contains about 50 to 5000  $\mu g$  of the fusion protein.

Attorney's Docker No.: 12071-003001 / SP-21 US

- 59. The method of claim 58, wherein the composition contains about 100 to 2000 µg of the fusion protein.
- 60. The method of claim 53, wherein the composition comprises about 500 µg of the fusion protein.
  - 61. The method of claim 53, wherein the composition is administered free of adjuvant.
  - 62. The method of claim 53, wherein the subject is a mammal.
  - 63. The method of claim 62, wherein the mammal is a human.
- 64. The method of claim 53, wherein the fusion protein is administered in an amount sufficient to reduce the size of the wart.
  - 65. The method of claim 53, wherein the wart is a genital wart.
  - 66. The method of claim 53, wherein the wart is an anogenital wart.
- 67. The method of claim 1, wherein the fusion protein comprises the Hsp60 protein and the HPV E7 protein.
  - 68. The method of claim 67, wherein the Hsp60 protein is a mycobacterial hsp.
- 69. The method of claim 68, wherein the mycobacterial hsp is a Mycobacterium bovis hsp.

Applicant: John R. Neefe et al., Attorney's Docket No.: 12071-003001 / SP-21 US

Serial No.: 09/891,823 Filed: June 26, 2001

Page : 20

70. The method of claim 69, wherein the *Mycobacterium bovis* hsp is *Mycobacterium bovis* BCG Hsp65.

- 71. The method of claim 67, wherein the HPV is a type 16 HPV.
- 72. The method of claim 67, wherein the composition contains about 50 to 5000  $\mu g$  of the fusion protein.
- 73. The method of claim 72, wherein the composition contains about 100 to 2000  $\mu g$  of the fusion protein.
- 74. The method of claim 67, wherein the composition comprises about 500  $\mu g$  of the fusion protein.
  - 75. The method of claim 67, wherein the composition is administered free of adjuvant.
  - 76. The method of claim 67, wherein the subject is a mammal.
  - 77. The method of claim 76, wherein the mammal is a human.
- 78. The method of claim 67, wherein the fusion protein is administered in an amount sufficient to reduce the size of the wart.
  - 79. The method of claim 67, wherein the wart is a genital wart.
  - 80. The method of claim 67, wherein the wart is an anogenital wart.